

MAINEGENERAL HEALTH

FUNCTIONAL AREA: Leadership

POLICY #: LD-13

EFFECTIVE DATE: 09/09

REVIEWED/REVISED: 10/09, 10/11,
11/13, 05/14, 05/15, 10/16, 03/17, 03/19

TOPIC: Management of the Activities of Non-Employed Contractors, Agents, Vendors, or Sales Representatives

AUTHORIZATION:

President/CEO MaineGeneral Health & MaineGeneral Medical Center

Chief Compliance Officer

Chief Operating Officer & CEO Long Term Care

Chief Medical Officer

Chief Human Resource Officer

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- I. PURPOSE:** This policy governs whom and under what circumstances non-employed clinical contractors, agents, contractors, vendors, or sales representatives, hereinafter called "Participants," may engage in providing services on site or the promotion and evaluation of products on behalf of MaineGeneral Health, hereinafter referred to as "MG."
- II. POLICY:** It is binding on Participants who provide or promote products and services and or MG personnel who evaluate such products and services, and it is applicable on MG premises as well as off-campus at MG-sponsored events.
- MG values the contribution made by Participants in an effort to improve the quality of patient care, and therefore MG offers coordinated access to Participants. Access is considered a privilege and therefore contingent on the Participant's compliance with MG policies and procedures set forth below.
- The Value Analysis Committee, Operating Room (OR) Value Analysis Committee, and the Pharmacy and Therapeutics Committee established these policies and procedures, which are also reviewed and endorsed by the Medical Executive Committee.
- III. RESPONSIBILITY:** It is the responsibility of the Purchasing Department, Pharmacy Department, Department Directors, Managers or designees to ensure the procedure of this policy is followed. In collaboration with the Director of Supply Chain / Support Services, the Ethics and Compliance department will monitor compliance via the Participant management program.

IV. PROCEDURE:

DEFINITIONS

Participants: Participants include non-employed providers, clinical contractors, manufacturers and suppliers, as well as sales representatives who promote goods and services on behalf of a manufacturer and/or supplier. MG classifies Participants on three levels, depending on the degree to which they are exposed to patients:

Level C: Participants who do not visit any patient care area and whose business is restricted to administrative offices and are escorted.

Level B: Participants who may visit any patient care area *except* operating rooms, heart catheterization labs, or angiography rooms.

Level A: Participants who may visit any patient care area *including* operating rooms, heart catheterization labs, or angiography rooms and may be within 3 feet of the sterile field

A. All Participants are required to register with MaineGeneral’s Participant credential system *prior* to engaging in providing any services, any informational activities or introduction of product or services. **NOTE: Even if Participant belongs to other systems, Participant must ensure registration on MG’s designated Participant management program site and have read and acknowledged the applicable MG’s procedures and policies.**

B. Participant Immunization and Screening Policy

Participants who visit MG, especially those who visit patient care areas, are at risk for exposure to and transmission of tuberculosis and vaccine-preventable diseases. The health and safety of Participants and the patients are central to MaineGeneral’s immunization and screening policy. **Refer to MGH Policy HR-26.**

To do business with MG, Participants must be registered and credentialed through the MG designated Participant management program.

In the event of an exposure incident, MG will monitor Participants and/or the companies they represent to confirm documentation of their immunization status which has been documented in the Participant management program.

Immunization and Screening Requirements

Level A & B Participants: See Immunization & Tuberculosis Screening Requirements outlined in below table.

Level C Participants: Must be free from known or suspected infectious disease(s) and have no fever (fever = 100.4°F/38.0°C or higher).

Participants are fiscally responsible for all costs associated with complying with these requirements.

**Participant Immunity, Immunization and Tuberculosis (TB) Screening Requirements
Applies to all Level A & B Participants**

(An “X” or explanation in any one of the boxes below indicates acceptable evidence of meeting the requirement)

<p>Acceptable Evidence of Immunity</p>	<p>Immunity: Laboratory evidence of immunity</p>	<p>Immunization: Acceptable Immunization Certification: (1) physician certificate of immunization or (2) school record including month + year or (3) military immunization record or (4) previous employer certificate of</p>	
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		immunization		
Rubella (German measles)	X	Two doses of live rubella vaccine, separated by at least four weeks, on or after 1 st birthday.	<i>If born before 1957, one dose of live Rubella vaccine</i> <u>OR</u> one dose of MMR vaccine	
Rubeola (measles)	X	Two doses of live measles vaccine, separated by at least four weeks, on or after 1 st birthday.	<i>If born before 1957, one dose of live measles vaccine</i> <u>OR</u> one dose of MMR vaccine	
Mumps	X	Two doses of live mumps vaccine, separated by at least four weeks, on or after 1 st birthday	<i>If born before 1957, one dose of live mumps vaccine</i> <u>OR</u> one dose of MMR vaccine	
Varicella (chicken pox)	X	Two doses of live chicken pox vaccine, separated by at least four weeks, on or after 1 st birthday		
Hepatitis B <u>If Bloodborne Pathogen Risk</u> Works with patients, in patient care environment, and may perform tasks with potential for exposure (OSHA category I or II)	X	Three doses of Hepatitis B vaccine- usually given @ 0,1, 6 months AND/OR documented laboratory evidence of +HepBSAb		Or a declination on file. <i>Individuals who decline Hepatitis B vaccination must have a signed declination on file with the company they represent using the terminology required by OSHA.</i>
Influenza		One dose per current vaccination season		Or a declination on file
Tuberculosis (TB) Symptoms of TB: Cough that lasts 3 or more weeks, blood in phlegm, weight		(1) Two documented TB skin tests (TST), at least 7 days apart, which were planted and read by a healthcare professional who routinely plants/reads TB tests (self-read not acceptable). One TST within the prior 12 month period and the other TST within 30 days prior to commencing work at MaineGeneral and remains symptom-free from		

loss, night sweats, fever, fatigue	<p>Tuberculosis; or</p> <p>(2) A single Blood assay for Mycobacterium Tuberculosis (BAMT) test within 30 days prior to commencing work at MaineGeneral and remains symptom-free from Tuberculosis; or</p> <p>(3) Documented history of a prior positive TST/BAMT <u>and</u> a documented recent negative chest x-ray (within 24 months) following the +TST/BAMT <u>and</u> remains symptom-free from Tuberculosis.</p>
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Immunization Exceptions and Declinations
A Participant may be exempt from MG’s immunization and screening requirements with the following documentation:

- A physician's written statement that immunization against one or more of these diseases is medically inadvisable for the Individual.
- The Individual’s written statement in opposition to immunization for sincere religious or philosophical reasons.

MG reserves the right to limit or deny access to any patient care area as a result of any exception or declination of any parts of this policy.

C. Participant Appointments

Participants who do business on MG premises must be registered and credentialed through MG designated Participant management program.

1. ***Make an appointment in advance*** to conduct business with MG personnel.
2. ***Provide a business card***, upon signing in for an appointment, which includes Participant name, company’s name, and the company’s address and phone number.
3. ***Sign in and out and obtain appropriate badge*** while on MG premises. Some individuals may be issued a MaineGeneral badge through Security for continued dates of service great than 90 days or as authorized by HR.
 - ***Participants*** must sign in and out utilizing the Participant management program access computers located in the main lobby of each campus.
 - ***Wear an identification badge*** so that it is plainly visible while they are conducting business on MG premises. Participants will be issued an identification badge upon signing in for an appointment. Participants who do not wear an identification badge may be escorted from the premises by any MG personnel. Violations to this requirement could result in suspension of Participant privileges.
 - ***Go directly to and from their appointment*** and may not loiter in any area outside of their appointment area.
 - ***Return identification badge*** when Participant signs out of their appointment.
 - In unique situations, a Participant may be issued a permanent identification badge for the sole purpose of providing supplies or services to designated departments after hours. For information, contact the Materials Management Department.
4. ***Be denied access to any patient-identifiable health information***, unless the company that the Participant represents has signed an agreement with MG that complies with the business associate provisions of the Health Insurance Portability and

Accountability Act ("HIPAA") which has been documented in the Participant management program or with Legal Services.

5. **Food Provisions**

Participants will not be allowed to provide food to any department unless it is being provided as part of a Participant sponsored educational in-service. Participants must obtain all food or beverage items from the MGMC Food Service Department and will not be allowed to bring in any food item from an outside source without prior permission from the Purchasing Department. Participants must contact the Food Service Department one week in advance of date needed and arrange for pre-payment of items requested.

D. **Conducting Business in Patient Care Areas**

1. Participants may not enter any patient care area at MG, including outpatient treatment areas, unless they have an appointment and have received approval and appropriate badging via Participant management system or Security Department.
2. Participants who are present during patient care rounds or diagnostic, surgical, and interventional procedures must comply with the following:
 - The Participant must be of legal age.
 - The Participant must provide documentation from a physician of their immune status, via the Participant management system.
 - The Participant must provide documentation, upon MG's request, from the company they represent that certifies the Participant's competency to observe, perform, or participate in the training, education, and or guidance in the use of any device, supply, or medication.
 - The Participant must comply with HIPAA provisions relating to patient information confidentiality, as described in this and other MG policies. **Refer to MGH Policy RI-02.**
 - The Participant must not wear fragrances on MG premises. For patient safety and comfort, MG has adopted a policy that prohibits staff and visitors from wearing fragrances or bringing in scented products.
 - The Participant must comply with any other requirements that MG applies.

All provisions of this policy apply to MG premises, educational conferences and events held off-campus where MG is the provider of Continuing Medical Education (CME) or Continuing Education Units (CEU).

3. **Physicians who request a Participant non-employed non-credentialed medical provider to provide patient care in patient care areas must:**
 - ***Obtain informed written consent*** from the patient before providing the Participant access to this setting. Consent can be part of the approved consent process for surgical, diagnostic, and interventional procedures if the consent forms include the activities of Participants. Physician should receive approval for this from the Medical Staff Office.
 - ***Supervise the activities of the Participant;*** such supervision is not a responsibility of the nurse or other hospital staff.

E. **Declaration of Patient Information Confidentiality**

1. MG is legally required under State and Federal laws, including, but not limited to, the Health Insurance Portability and Accountability Act (HIPAA), to protect the privacy of the Protected Health Information (PHI) of all patients treated at our facilities.
2. Participants' visits to MG may include contact with patients, viewing of computer-stored patient information, viewing information from patient medical records, and/or incidentally overhearing confidential conversations. Under no circumstances may this information be discussed with anyone, unless otherwise required by law.
3. Prior to providing any services at MG, a Participant must:
 - a. Have a signed Business Associate Agreement on file with MG's Participant management system or on file with Legal Services when Participants have direct patient contact or otherwise have access to Protected Health Information of MG patients. The Participant will print the Business Associate Agreement form located on MG's Participant management program site, fill out the form, have it signed by a duly authorized agent of Participant's company, and send the completed form to the MG Legal Department for processing. MG Legal will provide an executed copy of the Business Associate Agreement to the Participant, who will forward it to the Participant management program for inclusion in the Participant's profile.
 - b. Have permission from the HIPAA Privacy Officer and Chief Information Officer to access any of MG's electronic health record systems and sign the appropriate agreement to grant such access.

F. Conflict of Interest

1. To reinforce MG commitment to upholding the highest possible ethical standards and to foster greater transparency, MG has implemented a Conflict of Interest MGH Policy LD-23.
2. Conflict of Interest involves a situation in which any Participant has a financial or other personal consideration that may compromise, or have the appearance of compromising, their professional judgment or integrity in clinical care. If a Conflict of Interest exists, the Participant may not be allowed to do business at MG

G. Ethical Awareness

All clinicians and employees must adhere to MG's Code of Ethical Conduct policies with regard to Participants.

H. Excluded Parties

All Participants must maintain eligibility to do business with all federal and state healthcare programs such as Medicare, Medicaid (MaineCare) and TRICARE. In the event that a Participant is excluded from doing business with a federal or state healthcare program, Participant will immediately notify MaineGeneral.

I. Communicable Disease Precautions

To protect patients, staff and vendors from transmission of communicable disease within our organization, Participants must be free of potentially transmissible diseases and have no recent exposure to these diseases. Before any appointment with our MG staff, all Participants are reminded that compliance with hand hygiene and respiratory etiquette is

required while at MG. Any Participant with any signs of respiratory or GI illness will not be allowed in the facility.

J. Hazard Communication

In compliance with OSHA regulations, MG must make available to Participants, upon their request, a list of hazardous chemicals known to be present on the premises. A list is compiled for each individual work area. Participants may request a safety data sheet (SDS) through an individual unit or through MG's Material's Management Office.

K. Promotional Practices

1. Participants will not ship to any MG facility any supply, device, equipment or furniture either purchased or sample without first obtaining a valid Purchase Order Number. This number can only be obtained by contacting the MG Purchasing Department. **Refer to MGH Policy LD-6.** The exception to this policy would be for instrumentation needs that Sale Representatives would bring in at Surgeon or O.R. staff request. Since there is no charge for this instrumentation, a PO is not necessary. However, all Central Sterile protocols would be in effect.
2. Participants may not use MG personnel's pagers or cell phones to solicit them.
3. Participants may not set up a display on MG premises, unless it is approved by MG Marketing Department, or Clinical Education Department, and adheres to the following conditions:
 - It is part of a one or two-day educational conference sponsored by MG.
 - Its purpose is educational.
 - It provides reprints from evidence-based literature on the product.
 - It is continuously staffed by a representative who can provide product information.
4. Participants may not promote their product or service at general meetings or luncheons.
5. Participants may not promote their product or service at medical education programs, regardless of the program's sponsorship. Speakers sponsored by a manufacturer must present an unbiased approach to medical literature evaluation, product use, and/or research study design.
6. Participants may sponsor an off-campus site visit for MG personnel to evaluate a product or service, provided that:
 - The site visit is of significant business value to MG and advance notice given to Pharmacy or Materials Management Directors.
 - MG personnel participating in the site visit are directly involved in the decision-making for the selection of the product or service.
 - Provision of financial support for travel, lodgings, meals, and tips is reasonable by local standards. **Refer to MGH Policy LD-9.**
 - The Participant does not pay an honorarium or provide gifts to MG personnel for participating in the selection process or site visit, or for soliciting opinions in favor of the Participant's product or service. **Refer to MGH Policy LD-22.**
 - Any MG personnel who sponsors, endorses, or advocates for the selection of a particular product or service completes a conflict-of-interest disclosure. **Refer to MGH Policy LD-23.**

- The site visit does not violate MG's compliance program or HIPAA.
- 7. Participants may provide luncheons or meals (of nominal value by local standards) for educational meetings. If a Participant sponsors a meal or luncheon at an educational meeting, the following is prohibited before, during, or immediately after the meeting:
 - Speeches or product promotion by the Participant
 - Sales or product displays
 - Consultation fees paid to MG personnel for participation in a Participant-sponsored marketing or market-research initiative
 - Inclusion of MG personnel's spouses or other invited guests
 - The above functions/consults may occur but must be approved: Medical Staff functions/consults must be approved by the Medical Staff Office; Patient Services functions/consults approved by CNO; Other vendors approved by COO.
- 8. Participants may give MG personnel customary amenities, refreshment, or entertainment of nominal value, as long as such gifts are relevant to the business purpose and the time and place in which they are given, and they do not influence the recipient. **Refer to MGH Policy LD-22.**
 - The above may occur but must be approved: gifts to Medical Staff must be approved by the Medical Staff Office; gifts to Patient Services must be approved by CNO; gifts to areas other than medical staff or patient services must be approved by COO.

Government representatives may not give MG personnel such gifts.

- 9. Preceptorships are allowed, provided that all requirements in this policy and other MG and HIPAA policies are fulfilled.

L. Product Samples

Participants distributing product samples must comply with MG's Sample Drugs Policy and may not distribute samples to any individual clinician for personal or office-practice use on MG premises. **Refer to MGH Policy MM-7.**

M. Product Specification

1. Participants must comply with all federal laws and regulations and all applicable government-sanctioned lists with regard to the manufacture, sale, and distribution of medical devices. Medical devices and drugs being promoted must be approved by the FDA or Institutional Review Board.
2. Furnishings, bedding, and decorations must be manufactured and pass testing in accordance with Life Safety Code standards.

N. Appearance / Hygiene

Professional appearance and proper hygiene is an expectation of all individuals conducting business with MG.

O. Smoking

MG is a smoke-free organization and smoking is not allowed in any part of a MG facility or on its grounds. Additionally, Participants who smoke must ensure not to expose others to the odor of second hand smoke.

P. Property Removal

MGH property is for business use and should not leave the property without consent from a MGH Chief/officer or direct supervisor.

Q. Parking and Meeting Areas

Participant representatives must use the visitor's parking or designated Participant parking. Do not park in restricted areas. Cafeterias and vending areas are available for Participant's use. Lounges are off limits for Participants unless invited by hospital personnel.

R. Policy Enforcement

1. Participants who violate the provisions of this policy, policies on professional samples, and the Acquisition of Non-Capital Supplies, Services and equipment will receive a written warning from the Director of either Materials Management or Pharmacy Services. The Participant's immediate supervisor will receive a copy of the warning.
2. A second violation by the Participant will result in a one-year revocation of Participant privileges at MG, of which the Security Department will be notified.
3. MG personnel are encouraged to escort Participants who are not wearing an identification badge off the premises or to contact the Security Department.
4. MG personnel who knowingly violate the provisions of MG policies will be subject to disciplinary action executed by their respective department head, manager or division chief of service.

V. POLICY ACCESSIBILITY:

- Original approved MaineGeneral Health Policies are maintained in Administration at the ACH.
- Entities of MaineGeneral Health maintain and file policies specific to their areas in a designated Administrative area of their own.
- Copies of MGH policies are filed in the Health Sciences Library of the Thayer Center for Health, Waterville.
- Employees can access policies via the MaineGeneral Connect site.

VI. POLICY APPLIES TO:

- MaineGeneral Medical Center
- MaineGeneral Rehabilitation & Long Term Care
- MaineGeneral Retirement Community
- MaineGeneral Community Care
- All

VII. CITATIONS/BEST PRACTICE REFERENCES: (None.)

VIII. POLICY ATTACHMENTS:

- Attachment 1 - MGMC Vendor Conduct Agreement